

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Modak, et al.
Serial No. : To Be Assigned Examiner: To Be Assigned
Filed : July 30, 2003 Group Art Unit: To Be Assigned
For : COMBINATIONS OF ANTISEPTIC AND ANTIBIOTIC AGENTS
THAT INHIBIT THE DEVELOPMENT OF RESISTANT
MICROORGANISMS

INFORMATION DISCLOSURE STATEMENT

July 30, 2003

EXPRESS MAIL LABEL NO.: EV343636821US

Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

Mail Stop PCT

Dear Sir:

Pursuant to 37 C.F.R. §§1.97 and 1.98, applicants respectfully request that the documents listed below in reverse chronological order and on the accompanying PTO 1449 be considered by the Examiner and made of record in the above-referenced application. Copies of the documents listed are enclosed.

Several of the listed patent documents have been cited on the International Search Report for International Patent Application No. PCT/US02/03087, to which the present application claims priority. A copy of the International Search Report is also enclosed, which indicates the possible relevance of each document cited therein.

1. United States Patent No. 6,416,546 by Kimura et al., filed July 27, 2000, , issued July 9, 2002.
2. United States Patent No. 6,261,271 by Solomon et al., filed Jan. 13, 1998, issued July 17, 2001.
3. United States Patent No. 6,224,579 by Modak et al., filed Mar. 31, 1999, issued May 1, 2001.
4. United States Patent No. 6,106,505 by Modak et al., filed June 30, 1998, issued Aug. 22, 2000.
5. International Patent Application No. PCT/US00/08692 by The Trustees of Columbia University in the City of New York, filed March 30, 2000 published October 5, 2000 as WO 00/57933.
6. United States Patent No. 5,928,671 by Domenico, filed June 26, 1997, issued July 27, 1999.
7. United States Patent No. 5,902,283 by Darouiche et al., filed Mar. 26, 1997, issued May 11, 1999.
8. Huang and Stewart, "Reduction of polysaccharide production in *Pseudomonas aeruginosa* biofilms by bismuth dimercaprol (BisBAL) treatment," J. Antimicrob. Chemother. 1999, 44:601-605.
9. United States Patent No. 5,772,640 by Modak et al., filed Jan. 5, 1996, issued June 30, 1998.
10. United States Patent No. 5,707,366 by Solomon et al., filed June 7, 1995, issued Jan. 13, 1998.

11. European Patent Application No. EP 0 882 461 A2 of Unitika Ltd., filed June 4, 1998, published Dec. 19, 1998.
12. Raad, I. "Intravascular-catheter-related infections," *The Lancet*, 351:893-898.
13. United States Patent No. 5,688,516 by Raad et al., filed Oct. 3, 1994, issued Nov. 18, 1997.
14. United States Patent No. 5,624,704 by Darouiche et al., filed April 24, 1995, issued April 29, 1997.
15. Domenico et al., "Enhancement of bismuth antibacterial activity with lipophilic thiol chelators," *Antimicrob Ag Chemother*, 1997, 41:1697-1703.
16. Domenico et al., "Bismuth-dimercaprol exposes surface components of *Klebsiella pneumoniae* camouflaged by the polysaccharide capsule," *Ann NY Acad Sci*, 1996, 797:269-270.
17. United States Patent No. 5,451,424 by Solomon et al., filed Nov. 24, 1992, issued Sept. 19, 1995.
18. United States Patent No. 5,217,493 by Raad et al., filed March 11, 1992, issued June 8, 1993.
19. United States Patent No. 5,196,205 by Borody, filed June 12, 1990, issued March 23, 1993.
20. International Patent Application No. PCT/US93/02019, filed March 11, 1992, published Sept. 16, 1993 as International Patent Publication No. WO93/17746.

21. Sheretz et al., "Efficacy of antibiotic-coated catheters in preventing subcutaneous *Staphylococcus aureus* infection in rabbits," J. Infect Dis, 1993, 167:98-106.
22. United States Patent No. 5,165,952 by Solomon et al., filed Sept. 21, 1990, issued Nov. 24, 1992.
23. United States Patent No. 5,013,306 by Solomon et al., filed Mar. 21, 1990, issued May 7, 1991.
24. United States Patent No. 4,999,210 by Solomon et al., filed Dec. 7, 1989, issued Mar 12, 1991.
25. Domenico et al., "Reduction of capsular polysaccharide and potentiation of aminoglycoside inhibition in gram-negative bacteria by bismuth subsalicylate," J. Antimicrob., 1991, 28:801-810.
26. Bierer, "Bismuth subsalicylate: history, chemistry, and safety." Rev. Inf. Dis., 1990, 12 Suppl 1:S3-S8.
27. León-Barúa et al., "In vitro and in vivo effects of three bismuth compounds in fermentation by colonic bacteria," Rev. Inf. Dis., 1990, 12 Suppl 1:S24-S29.
28. Goodman and Gilman's The Pharmacological Basis of Therapeutics, Gilman et al., editors, Seventh Edition, 1985, Macmillan Publishing Company, New York, pp 959-960, 1066-1067, 1171.
29. United States Patent No. 4,064,238 by Bocher et al., filed August 21, 1975, issued December 20, 1977.

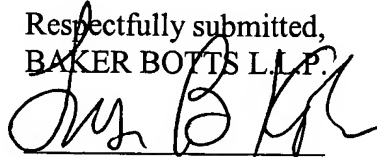
Enclosed are a copy of US 5,624,704 (Ref.# 14) and US 6,416,546 (Ref.# 1) which, as set forth on page 3 of the International Search Report, correspond to US 5,902,283 (Ref.# 7) and EP 0 882 461 (Ref.# 11), respectively. Also enclosed are a copy of US 5,451,424 (Ref.# 17), US 5,165,952 (Ref.# 22), US 5,013,306 (Ref.# 23), US 6,261,271 (Ref.# 2) and US 4,999,210 (Ref.# 24), which, as set forth on page 3 of the International Search Report, correspond to US 5,707,366 (Ref.# 10). In addition, applicants enclose a copy of US 6,224,579 (Ref.# 3) and US 5,217,493 (Ref.# 18) which, as set forth on page 3 of the International Search Report, correspond to WO00/57933 (Ref.# 5) and WO93/17746 (Ref.# 20), respectively.

Identification of the listed documents is not to be construed as an admission of the applicants or attorneys for applicants that such citations are available as “prior art” against the subject application. If the Examiner applies the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute “prior art” under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

There should be no fee required for this submission. However, if any fee is required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this paper is enclosed.

Respectfully submitted,
BAKER BOTTS L.L.P.

A handwritten signature in black ink, appearing to read 'Lisa B. Kole', is written over a horizontal line.

Lisa B. Kole
PTO Reg. No. 35,225

Attorneys for Applicants
(212) 408 2500

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Atty. Docket No. A33459-PCT-USA-A 070050.1365	Serial No. To Be Assigned
	Applicant Modak et al.	
	Filing Date July 29, 2003	Group To Be Assigned

U.S. PATENT DOCUMENTS

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*Exam. Init.			Document No.						Date	Name	Class	Subclass	Filing Date if Appro.	
	1		6	4	1	6	5	4	6	7/9/02	Kimura et al.	623	1.46	
	2		6	2	6	1	2	7	1	7/19/01	Solomon et al.	604	265	
	3		6	2	2	4	5	7	9	5/1/01	Modak et al.	604	265	
	4		6	1	0	6	5	0	5	8/22/00	Modak et al.	604	265	
	6		5	9	2	8	6	7	1	7/27/99	Domenico	424	653	
	7		5	9	0	2	2	8	3	5/11/99	Darouiche et al.	604	265	
	9		5	7	7	2	6	4	0	6/30/98	Modak et al.	604	265	
	10		5	7	0	7	3	6	6	1/13/98	Solomon et al.	604	265	
	13		5	6	8	8	5	1	6	11/18/97	Raad et al.	424	409	
	14		5	6	2	4	7	0	4	4/29/97	Darouiche et al.	427	2.24	
	17		5	4	5	1	4	2	4	9/19/95	Solomon et al.	427	2.1	
	18		5	2	1	7	4	9	3	6/8/93	Raad et al.	623	11	
	19		5	1	9	6	2	0	5	3/23/93	Borody	424	653	
	22		5	1	6	5	9	5	2	11/24/92	Solomon et al.	427	2	
	23		5	0	1	3	3	0	6	5/7/91	Solomon et al.	604	265	
	24		4	9	9	9	2	1	0	3/12/91	Solomon et al.	427	2	
	29		4	0	6	4	2	3	8	12/20/77	Bocher et al.	424	227	

NY02:451285.1 Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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FOREIGN PATENT DOCUMENTS

Document No.									Date	Country	Class	Subclass	Translation Yes No	
5		0	0	5	7	9	3	3	10/5/00	WIPO				
11		0	8	8	2	4	6	1	12/19/98	Europe				
20		9	3	1	7	7	4	6	9/16/93	WIPO				

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)

8		Huang and Stewart, "Reduction of polysaccharide production in <i>Pseudomonas aeruginosa</i> biofilms by bismuth dimercaprol (BisBAL) treatment," J. Antimicrob. Chemother. 1999, 44:601-605.
12		Raad, I. "Intravascular-catheter-related infections," The Lancet, 351:893-898.
15		Domenico et al., "Enhancement of bismuth antibacterial activity with lipophilic thiol chelators," Antimicrob Ag Chemother, 1997, 41:1697-1703.
16		Domenico et al., "Bismuth-dimercaprol exposes surface components of <i>Klebsiella pneumoniae</i> camouflaged by the polysaccharide capsule," Ann NY Acad Sci, 1996, 797:269-270.
21		Sheretz et al., "Efficacy of antibiotic-coated catheters in preventing subcutaneous <i>Staphylococcus aureus</i> infection in rabbits," J. Infect Dis, 1993, 167:98-106.
25		Domenico et al., "Reduction of capsular polysaccharide and potentiation of aminoglycoside inhibition in gram-negative bacteria by bismuth subsalicylate," J. Antimicrob., 1991, 28:801-810.
26		Bierer, "Bismuth subsalicylate: history, chemistry, and safety." Rev. Inf. Dis., 1990, 12 Suppl 1:S3-S8.
27		Leon-Barau et al., "In vitro and in vivo effects of three bismuth compounds in fermentation by colonic bacteria," Rev. Inf. Dis., 1990, 12 Suppl 1:S24-S29.

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	28		Goodman and Gilman's The Pharmacological Basis of Therapeutics, Gilman et al., editors, Seventh Edition, 1985, Macmillan Publishing Company, New York, pp 959-960, 1066-1067, 1171.

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